Environmental Assessment

1. **Date**

November 14, 2011

2. **Name of Notifier**

CDG Environmental, LLC

3. **Address**

205 Webster St., Bethlehem, PA 18015

4. **Description of Proposed Action**

This FCN requests that FDA approve the use of an aqueous solution of chlorine dioxide described in FCN 1011 and FCN 1052 in concentrations not to exceed 3 ppm residual (determined by Method 4500-ClO2-E) as an antimicrobial agent in the following applications:

- As a spray or a dip in the processing of poultry, red meat, red meat parts and organs
- On processed, comminuted, or formed meat food products (unless precluded by the standards of identity in 9 CFR 319) prior to packaging of food for commercial purposes
- On raw agricultural commodities in the preparing, packaging or holding of food for commercial purposes
- In water and ice that are used to rinse, wash, thaw, transport or store seafood

The above uses are regulated under 21 CFR 173.325, Acidified Sodium Chlorite Solutions. Upon acid activation, sodium chlorite solutions will generate chlorine dioxide to a greater or lesser extent, depending upon the pH of the final use solution. FDA already approves aqueous solutions of acidified sodium chlorite and chlorine dioxide with chlorine dioxide concentrations as high as 200 ppm. Data shows that the levels of chlorine dioxide and chlorite that occur following the use instructions in 21 CFR 173.325 are equivalent to or greater than the levels that will result from the chlorine dioxide generation method for this FCS. Consequently, this FCN will not result in any new or increased environmental risks.

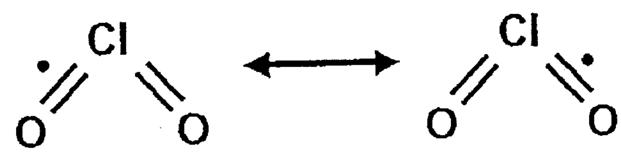
As described in US Patent Number 6,824,756 B2, the Gas:Solid process produces high purity chlorine dioxide by passing chlorine gas through thermally stable solid sodium chlorite. The chlorine dioxide product thus produced meets the 90% minimum purity requirement in Section 173.300. These systems do not require the use of any chemical activators, and do not generate any unique impurities or byproducts. As they cannot exist as a gas, chlorites, chlorates, and chlorides remain in the reactor vessel, and only pure chlorine dioxide is produced and dissolved in water to produce the FCS.

5. Identification of Chemical Substances that are the Subject of the Proposed Action

a) Chemical Information for the Notified Chemical

1) Chemical Name	Chlorine Dioxide
2) Synonyms	Chlorine Oxide, Chlorine (IV) Oxide
3) CAS Registry Number	10049-04-4
4) Chemical Formula	ClO2

5) Structure



6) Properties

Melting Point	-59°C
Boiling Point	11°C
Solubility (aqueous)	8 gm/ l at 20°C

b) Method of Production

The method for production of the thermally stabilized sodium chlorite precursor is described in US Patent Number 6,824,756 B2. A description of the manufacturing process for the Notifier's FCS is considered to be confidential business information.

c) Use Rates

The Notifier is proposing that chlorine dioxide be applied as an aqueous solution to the food commodities listed in Section 4 of this EA, in an amount not to exceed 3 ppm residual chlorine dioxide. To maintain a residual of 3 ppm, it is necessary to feed the FCS at some higher level to allow for the ongoing reaction with food and food micro-organisms. The precise amount of excess chlorine dioxide depends on the demand of the process and the degree of decontamination desired. In any case, the Notifier does not expect maximum feed rates to be higher than 5-10 ppm.

d) Impurities

The impurities associated with chlorine dioxide are a function of the generation system. The Notifier's chlorine dioxide generation system produces a gas which is 99.7+% pure. The reaction to produce this gas is,

$$2\ NaClO_2 + Cl_2 \rightarrow 2\ ClO_2 + 2\ NaCl$$

Thus, only sodium chloride is produced by the reaction, and that is a solid remaining in the reactor vessel along with the impurities in the technical grade sodium chlorite.

The water into which this gas is dissolved meets or exceeds ASTM D-19 Standard D5127-90 for Type E-III water.

Thus, very little in the way of impurities remain in the final product. Impurities associated with other methods of generating chlorine dioxide are unreacted sodium chlorite, activation acid, chloride ion, and chlorate ion. None of these are present in the Notifier's product.

The 0.3% solution prepared from chlorine dioxide produced by this method is then further diluted with water to the required dosage strength, and then applied to the food items listed in Part 4.

6. Introduction of Substances into the Environment

a) Manufacturing Process

The chlorine dioxide is produced at the Notifier's manufacturing facility. Releases of substances into the environment are not anticipated under normal manufacturing conditions. The manufacturing area is secured, and releases of the FCS are captured and neutralized with sodium thiosulfate prior to discharge into the local sanitary sewer.

Likewise, no releases are anticipated in the manufacture of the precursor product, Saf-T-Chlor, to the FCS. In this case, raw powder fines and spilled product are captured and recycled through the process. Any residual raw powder or product remaining in the manufacturing equipment is washed to the local sanitary sewer.

Discharges of up to 5,000 lbs. of wash down water with contaminants are permitted per day by the local authority.

Consequently, because information available to the best knowledge of the Notifier does not suggest that the manufacture of the FCS poses any extraordinary circumstances in this case indicative of any adverse environmental impact, discussion about the manufacturing site and compliance with relevant emissions requirements is not provided here.

b) Use Releases

The uses for chlorine dioxide generated by the proposed method are identical and substitutive for uses of chlorine dioxide by already approved methods. They yield no new or significantly different releases with respect to the currently approved uses. The only differences are related to the impurities inherent to the generation chemistry as shown in Table 1.

Table 1 – ClO2 Composition

Parameter	Gas:Solid	PureLine PureClO2	Halox H 2000
ClO2 Production Rate	8 – 200 lb/day	7 – 30 lb/day	5.5 lb/day
ClO2 Concentration	<8%	Variable	575 ppm
ClO2 Purity	>99.7%	>99%	>93.75%
Chlorine in ClO2	< 0.3%	< 0.5%	0
Other Impurities	None	None	Chlorite: 3.7% Chlorate: 2.8%

In addition to chlorine dioxide, other generation methods have the potential to produce the following in the effluent stream: Sodium chlorite, sodium chlorate, sodium hydroxide, hydrogen, and chlorine. None of these are present in the Notifier's FCS. Finally, the increase in concentration of sodium ion in process water should be near zero, since only chlorine dioxide is present in the FCS. This is significantly lower than under the existing use as regulated by 21 CFR 173.325.

Environmental releases from the use of the FCS may occur to both water and air.

Water Releases - The released substances include chlorine dioxide, chlorite ion and chlorate ion. The FCS solution which is the subject of the EA is produced at the Notifier's manufacturing plant and shipped to the use point before application in the meat and produce processing facilities. The releases of these species are expected to be less than those already approved under 21 CFR 173.325.

Chlorine dioxide will reduce to chlorite, chloride, and chlorate when exposed to organic material. It will reduce to chlorine and oxygen when exposed to UV radiation. Further, because these oxychlorine species readily react with organic matter in water and soil, they will undergo degradation into chloride ions.

Releases to the aquatic environment are not expected for chlorine dioxide since this substance should either be destroyed by oxidation with organic matter, exposure to UV radiation, or by the wastewater treatment system at the facility using chlorine dioxide. If the facility discharges directly to a sanitary sewer, it is anticipated that the high organic loads of the receiving wastewater stream for POTW water treatment facilities would result in very rapid reduction of the species to innocuous levels of chloride.

In previously approved generation techniques, both unreacted feedstock and reaction byproducts formed during generation are present in the product stream. As shown in Table 1 the Gas:Solid technology offers the advantage that only sodium chloride is a byproduct of generation, and even then, sodium chloride remains in the reactor vessel and does not carry over into the product stream.

Maximum wastewater concentrations of chlorite and chlorate ions can be estimated using the following assumptions:

- Maximum application rate is 10 ppm
- Chlorine dioxide is completely converted to chlorite and chlorate in a 70/30 ratio[1]
- No chlorite impurity in the FCS

Therefore, the maximum concentration of chlorite in wastewater is:

$$10 \text{ ppm} \times 0.7 + 0 = 7 \text{ ppm}$$

And the maximum concentration for chlorate is:

$$10 \text{ ppm} \times 0.3 = 3 \text{ ppm}$$

The estimated environmental concentrations (EEC's) for facilities that discharge directly into an aquatic body can be calculated using the following assumptions:

- Approximately 50% of the total waster discharged from a food processing plant is treated with chlorine dioxide[2,3]
- The receiving stream dilution factor is 10[4]
- Chlorite removal/destruction by wastewater treatment at the food processing plant is 99%[5]

Therefore, the maximum EEC for chlorite is:

$$7 \text{ ppm} \times .5 \times (1-0.99) \times 0.10 = 0.0035 \text{ ppm or } 3.5 \text{ ppb}$$

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[1] Werdehoff, K. S., and Singer, P. C., *Chlorine Dioxide Effects on THMPP, TOXFP, and the Formation of Inorganic By-Products.* Journal AWWA, September, 1987.

[2] United States-Asia Environmental Partnership; Civil Engineering Research Foundation. Clean Technologies in US Industries: Focus on Food Processing.

[3] Graham, M.D., Strasser, J., Mannapperuma, J.D., *Application of Ozonation and Membrane Treatment in Poultry Processing;* 400-02-023F; California Energy Commission , 2002

[4] EPA has provided a "7Q10" dilution factor of 24 for POTW's. Thus, this is a worst case scenario.

[5] Toxicological Profile for Chlorine Dioxide and Chlorite, Agency for Toxic Substances and Disease Registry, http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf

And the maximum EEC for chlorate (assuming no removal by wastewater treatment) is:

$$3 \text{ ppm} \times 0.5 \times 0.1 = 0.150 \text{ ppm or } 150 \text{ ppb}$$

Using similar methodology, chlorite and chlorate EEC's for facilities that discharge untreated wastewater to POTW's that subsequently treat wastewater prior to aquatic discharge are expected to be lower since there is an additional dilution factor from other users of the POTW.

Air Releases - Air releases of chlorine dioxide may occur during use of this substance due to its known volatility. The most significant method for air release is with rapid agitation of the concentrated solution. Workplace exposures to chlorine dioxide vapors are regulated by the Occupational Safety and Health Administration (OSHA). OSHA has set a Permissible Exposure Limit (PEL) for chlorine dioxide at 0.1 ppm (0.3 mg/m^3) TWA for 8 hours. The Short Term Exposure Limit (STEL) is set by NIOSH at 0.3 ppm (0.9 mg/m^3) for any 15 minute duration over a 10 hour workday. If the FCS is used as intended and according to label directions, the Notifier does not expect limits will be exceeded. In addition, the MSDS for the FCS identifies the inhalation hazard associated with chlorine dioxide and provides these limits. Furthermore, workers handling this FCS are instructed to wear a respirator if exposure limits are exceeded.

Terrestrial Releases – EPA has published a statement on terrestrial environmental risk assessment which says, "The rapid degradation of the chemicals, coupled with the generally low toxicity of chlorine dioxide and sodium chlorite to birds and mammals, make risk to these organisms unlikely. The very limited data available to assess the phytotoxicity of chlorine dioxide/ sodium chlorite make it difficult to determine the risk to terrestrial/semi-aquatic plants".[6] The ERG stated in FCN 668, "Rapid degradation of the chemicals is also expected to prevent toxicity in soil dwelling organisms such as earthworms.[7]

7. Environmental Fate of Emitted Substances

Sodium chlorite, sodium chlorate, and chlorine dioxide released into the environment will likely undergo reduction in contact with organic matter, inorganic chemical reactions. Ultimately these oxychlorine species will be reduced to the chloride ion.

Air – Upon rapid agitation of the Notifier's FCS some free chlorine dioxide will be released from the solution. This may result in the volatilization of, at most, trace amounts of chlorine dioxide into the air. The amount of chlorine dioxide available is 0.025 lbs. per gallon of the FCS. In an open environment, this will quickly be diluted by the surrounding air. Chlorine dioxide in air also readily undergoes photochemical

[6] *Registration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case 4023)*; EPA 738-R-06-007; USEPA; Office of Pesticide Programs: Washington, DC, August 2006.
[7] White, K. E., *Environmental Decision Memo for Food Contact Notification No. 000668*, USFDA; Division of Chemistry Research and Environmental Review; Washington, DC, December 6, 2006.

decomposition.[8] This results in molecular chlorine and oxygen, followed by a reduction of chlorine to chloride. As a result, a release of the FCS is expected to decompose and dissipate rapidly, with the formation of chloride.

Freshwater, marine and estuarine ecosystems - Chlorine dioxide and chlorite are the substances of environmental concern which might be released into aquatic environments. If used in accordance with the labeled instructions for the proposed use, the possibility of the release of toxic substances into aquatic environments in harmful quantities is remote. Discharges from a food processing operation would go to either the plant wastewater facility or to a municipal sewer for treatment prior to release. Chlorine dioxide and chlorite would both be eliminated through reactions with inorganic and organic compounds as described in Section 6. The predominant chlorine form expected to eventually result from the various reactions is the chloride ion. Additionally, photochemical decomposition of chlorine dioxide and biodegradation of chlorine dioxide and chlorite would be expected.

Reactions with Inorganic Compounds - In aqueous solutions at or below pH 7, chlorine dioxide reacts with iron and manganese to oxidize the metal and reduce chlorine dioxide to chloride. At pH above 7, where the chlorite ion might predominate, salts of ferrous iron and manganese are oxidized by sodium chlorite.

Reactions with Sulfides – Sulfides readily react with chlorine dioxide and chlorite; the exact reactions are dependent upon pH and other factors.

Reactions with Ammonia and Amines – In waters containing ammonia and primary amines, no residual oxidants corresponding to chloramines are formed since chlorine dioxide does not react with ammonia and primary amines.[9]

Reactions with Organic Compounds - In general, chlorine dioxide reacts with organic compounds by the addition of oxygen rather than by the addition of chlorine. This preference for the addition of oxygen to organic compounds is the principle reason that chlorine dioxide has become the disinfectant of choice for some drinking water and wastewater treatment facilities. For these uses, the formation of trihalomethanes and other toxic or carcinogenic chlorinated organic compounds is significantly reduced or eliminated by the use of chlorine dioxide instead of chlorine. The reactions of organic compounds in red meats are expected to be the same as those which occur from the chlorine dioxide treatment of drinking water and wastewater. Since chlorine dioxide is highly reactive, it will readily react with the organic matter and microorganisms on the meat surfaces and will be reduced to chlorite, chloride, and chlorate. Chlorite and chlorate will also readily react with organic matter and microorganisms and will ultimately degrade into chloride ions. The Notifier expects the environmental concentrations for these oxychlorine species will be very small.

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[8] Gordon, G., Kieffer, R.G., and Rosenblatt, D. H., *The Chemistry of Chlorine Dioxide* , Progress in Inorganic Chemistry, Vol. 15, 1972

[9] White, G. C., *Handbook of Chlorination*, p. 603, Van Nostrand Rheinhold Co., 1972.

8. Environmental Effects of Released Substances

21 CFR 173.325 already approves several variations of acidified sodium chlorite containing chlorine dioxide in concentrations of up to 200 ppm as described in FCN 450, 739, and 787. Also, in GRN 62 and 161, chlorine dioxide is approved for use in packaging material as a preservative, and is considered GRAS. FCN 668 describes the use of chlorine dioxide produced by electrochemical means in amounts not to exceed 3 ppm for uses listed in 21 CFR 173.325.

The Notifier anticipates that the proposed method of generation and resultant FCS will encourage replacement of acidified sodium chlorite in smaller systems where lower usage rates would not support the costs associated with installation of conventional generators. Also, as none of the harmful byproducts of previously approved generation methods are present in the Notifier's FCS, environmental effects should be much less than with previously approved methods.

For purposes of the Registration, Data Call-in and Re-registration programs for pesticide products regulated under the Federal Insecticide, Fungicide and Rodentcide Act, the EPA has determined that the potential health and environmental effects for chlorine dioxide and chlorite are essentially identical.

Air - It is believed that no significant impact on the health of human beings or other organisms would occur by approval of the proposed usage. This is due to the extremely low potential for the release of significant quantities of chlorine dioxide into the air and due to the expected photochemical decomposition of chlorine dioxide in air.

Freshwater, marine and estuarine ecosystems – EPA has concluded that chlorine dioxide is significantly less toxic to aquatic organisms than chlorine.[10]

The toxic effects of chlorine dioxide, chlorite, and chlorate on aquatic organisms have been studied and numerous reports are available in the literature. The EPA re-registration eligibility documents (REDS) for chlorine dioxide, chlorite, and inorganic chlorates provide a complete discussion of the available data. The REDs and database listings for the toxicology literature are available on the internet as Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (CASE 4023); EPA 738-R-06-007; Washington, D.C., Aug. 2006.
http://www.epa.gov/pesticides/reregistration/REDs/chlorine dioxide_red.pdf.

[10] *Reregistration Eligibility Document for Sodium and Calcium Hypochlorite Salts*, February 1992; NTIS Report No. 540/RS-92-193

FDA has produced tables summarizing the environmental toxicity for chlorites and chlorates as shown below.

Table 2. Summary of Environmental Toxicity Endpoints for Chlorite[11]

Species	LC50 or EC50 (mg/L)	NOEC (mg/L)
Freshwater Fish	50.6 – 420	32 – 216
Freshwater Invertebrates	0.027 – 1.4	0.003 – 0.4
Estuarine/Marine Fish	75	13.9
Estuarine/Marine Invertebrates	0.576 – 21.4	14.3
Aquatic Plants	1.32	<0.62

Table 3. Summary of Environmental Toxicity Endpoints for Chlorate[12]

Species	LC50 or EC50 (mg/L)	NOEC (mg/L)
Freshwater Fish	7.3 – 1100	600 – 1000
Freshwater Invertebrates	2100 – 4100	52 – 1000
Aquatic Plants	133 – 444	50 - 3137

From the estimated release rates developed in Item 6, the release of the FCS into terrestrial ecosystems would have minimal effects. Chlorine dioxide reaching the ground would quickly react and degrade to chloride according to the chemical reactions and physical mechanisms which have been previously discussed. No threats to groundwater would be anticipated. Bio-accumulation would not occur in either plants or animals.

The data available strongly suggests that the amounts of the oxychlorine species which would be expected to be released into the environment through use and disposal of the FCS would be low as to pose no threat to either aquatic or terrestrial ecosystems.

9. Use of Resources and Energy

The production of the FCS using the Notifier's method will replace existing methods of generation, and is not expected to result in increased use of natural resources. The use of an 80% sodium chlorite precursor should reduce the energy requirement for manufacture of both containers for the substance and the substance itself. The energy required to manufacture the other precursor, chlorine, should more than be offset by the reduction in energy for multiple secondary precursors required in already approved methods of

[11] Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA-HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington D.C., Aug 2, 2006

[12] Anderson, B.; Hetrick, J. A.; Nelson, H. Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses. Reregistration Case Number 4049; Docket ID No. EPA-HQ-OPP-2005-0507; U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances: Washington, D.C., Jan 31, 2005.

generation. The application of the FCS should also require less energy than already approved methods. The use of the FCS is not expected to require additional natural resources during its use or disposal of wastes containing the FCS or its degradates.

10. Mitigation Measures

As no adverse environmental effects are anticipated, mitigation measures are not required.

11. Alternatives to Proposed Action

Alternatives to the proposed action need not be considered because no potentially adverse effects have been identified.

12. List of Preparers

This assessment was prepared by Michael J. Kaszyski, PE of CDG Environmental, LLC. Mr. Kaszyski holds engineering degrees in Mechanical, Civil, and Industrial Engineering as well as Business Administration. He has over 35 years of experience in various aspects of water and wastewater treatment.

13. Certification

The undersigned certifies that the information presented is true, accurate and complete to the best knowledge of CDG Environmental, LLC.

Name: Michael J. Kaszyski

Title: Chief Engineer, CDG Environmental, LLC

Signature: [redacted]